REMARKS

The Office action of March 25, 2005, has been carefully considered.

Claims 1 through 33 have been rejected under 35 USC 103(a) over Jamin.

It is noted initially that the method claims in this application have been amended to recite the step of oral administration, and the composition claims have been amended to recite that the composition is for oral administration. These amendments have clear support in the specification, particularly at page 1, line 14.

The Office action states that Jamin discloses a combination of 5 mg/day of nomegestrol acetate and estradiol, and states that the difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of nomegestrol and estradiol in a single composition.

However, that is very clearly not the *only* difference between the claimed invention and the art. As noted in the Office action, Jamin teaches administration of 5 mg/day of nomegestrol acetate, whereas Claims 1 and 13 recite administration of about 1.5 to 3.75 mg of nomegestrol acetate, and Claims 17 and 29 recite administration of about 0.1 to about 2.5 mg of nomegestrol acetate. The amount of nomegestrol acetate taught by Jamin therefore does not fall within the presently claimed ranges, and the claimed amount is at least 25% less than the amount disclosed by Jamin.

Moreover, the claimed invention teaches simultaneous administration of about 0.3 mg to about 3 mg of estradiol, an ester thereof or an equine conjugated estrogen, and the Office action does not even take any position as to whether the amount disclosed by Jamin falls within the claimed range.

LAW OFFICES
DENNISON, SCHULTZ, DOUGHERTY & MACDONALD
SUITE 105
1727 KING STREET
ALEXANDRIA, VIRGINIA 22314-2700
703 837-9600

Submitted herewith is an opinion declaration from Dr. Jean-Louis Thomas, an inventor of this application, in which he states that Jamin teaches that the effective dose of nomegestrol acetate for achieving contraception is 5 mg daily. Dr. Thomas further states that the small dose of percutaneous estradiol disclosed by Jamin, 50 µ per day, is necessary for avoiding bleeding pattern abnormalities observed with the high dosage of oral nomegestrol acetate. It is noted here that the 50 µg per day administration is not within the presently claimed range for estradiol.

Moreover, Dr. Thomas states that the combination of the *oral* nomegestrol acetate with the *oral* estradiol not only results in a good bleeding pattern, but also enhances the contraceptive efficacy of nomegestrol acetate, as described in the specification at page 22, line 31 to page 23, line 11, and shown in Table 1 on page 35. This dosage of estradiol thus potentiates the nomegestrol acetate, an effect which has not been previously demonstrated.

Thus, the present invention is based upon the discovery that nomegestrol acetate is potentiated by oral estradiol, both hormone components of this combination acting to suppress the secretion of pituitary hormones (i.e. gonadotropins, LH and FSH) involved in follicular growth and ovulation. The potentiation discovered and reported in this application allows the use of nomegestrol acetate and contraception at a lower dosage than the single dose of 5 mg taught by Jamin.

Thus, the difference between the claimed invention and the disclosure of Jamin is not merely simultaneous oral administration of nomegestrol acetate and estradiol, but rather the use of a lower dosage of nomegestrol acetate and a higher dosage of estradiol, which has been found to potentiate the nomegestrol acetate to enhance the contraceptive efficacy

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SUITE 105
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of nomegestrol acetate and the suppress the secretion of pituitary hormones.

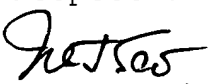
Withdrawal of this rejection is requested.

Claims 1 through 33 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting over Claims 18 and 21 through 32 of U.S. Patent Application Serial No. 09/423,108.

This patent application has now issued as U.S. Patent No. 6,909,049, and Applicants submit herewith a Terminal Disclaimer to obviate the double patenting rejection over this prior patent. Withdrawal of this rejection is requested.

In view of the foregoing amendments and remarks, Applicants submit that the present application is now in condition for allowance. An early allowance of the application with amended claims is earnestly solicited.

Respectfully submitted,



Ira J. Schultz
Registration No. 28666

LAW OFFICES
DENNISON, SCHULTZ, DOUGHERTY & MACDONALD
SUITE 105
1727 KING STREET
ALEXANDRIA, VIRGINIA 22314-2700
703 837-9600